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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/713,642

11/13/2003

David S. F. Young

2056.026

1647

21917

7590

12/13/2006

MCHALE & SLAVIN, P.A.

2855 PGA BLVD

PALM BEACH GARDENS, FL 33410

EXAMINER

REDDIG, PETER J

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 12/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/713,642

Applicant(s)

YOUNG ET AL.

Examiner

Peter J. Reddig

Art Unit

1642.

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22, 25-28, 30-32 and 34 is/are pending in the application.
- 4a) Of the above claim(s) 1-22, 25 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27, 28, 30-32, and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The Amendment filed November 7, 2006 in response to the Office Action of August 7, 2006 is acknowledged and has been entered. Previously pending claims 29 and 33 have been cancelled, claims 27, 28, and 34 have been amended.
2. Claims 1-22, 25-28, 30-32, and 34 are pending.
3. Claims 1-22, 25, and 26 remain withdrawn from consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions.
4. Claims 27, 28, 30-32, and claim 34 only as it is drawn to the species cytotoxic moieties are currently under consideration,
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
6. The following rejections are being maintained:

Claim Rejections - 35 USC 112

7. Claims 27, 28, 30-32, and 34 remain rejected under 35 USC 112 for the reasons previously set forth in section 8 pages 4-12 in the Office Action of August 7, 2006 and the following.

Applicant argues that real word utility for the PTA-4622 hybridoma cell line, and for the isolated monoclonal antibody produce by the hybridoma cell line identified as H460-22-1, and deposited with the ATCC as Accession Number PTA-4622, can be evidenced in S.N.

11/321,624, filed December 29, 2005. Applicant argues that the '624 application evidences binding to CD-63 on a variety of cancer cells and cytotoxicity mediation of cells evidencing surface expression of CD63.

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Applicant's arguments have been carefully considered, but have not been found persuasive.

Examiner has established a priority date for the instant application, 10/713,642, of 11/29/2000 from application 09/727,361, now patent 6,657,048. Although the 09/727,361 is a continuation in part of application, 09/415,278, the 09/415,278 application does not recite the claimed antibody.

Although Applicant argues that real word utility for the PTA-4622 hybridoma cell line, and for the isolated monoclonal antibody produce by the hybridoma cell line identified as H460-22-1, and deposited with the ATCC as Accession Number PTA-4622, can be evidenced in S.N. 11/321,624, filed December 29, 2005, enablement is required at the time the application was filed.

The MPEP teaches in section 2164.05 (a) that:

The state of the art existing at the filing date of the application is used to determine whether a particular disclosure is enabling as of the filing date. >*Chiron Corp. v. Genentech Inc.*, 363 F.3d 1247, 1254, 70 USPQ2d 1321, 1325-26 (Fed. Cir. 2004) ("a patent document cannot enable technology that arises after the date of application").< Publications dated after the filing date providing information publicly first disclosed after the filing date generally cannot be used to show what was known at the time of filing. *In re Gunn*, 537 F.2d 1123, 1128, 190 USPQ 402,405-06 (CCPA 1976); *In re Budnick*, 537 F.2d 535, 538, 190 USPQ 422, 424 (CCPA 1976) (In general, if an applicant seeks to use a patent to prove the state of the art for the purpose of the enablement requirement, the patent must have an issue date earlier than the effective filing date of the application.). While a later dated publication cannot supplement an insufficient disclosure in a prior dated application to make it enabling, applicant can offer the testimony of an expert based on the publication as evidence of the level of skill in the art at the time the application was filed. *Gould v. Quigg*, 822 F.2d 1074, 1077, 3 USPQ2d 1302, 1304 (Fed. Cir. 1987)

Thus, an application must be enabled as of the filing date of the application and the reference to application 11/321, 624, filed December 29, 2005, does not enable the instant application.

Further, although applicant argues that the antibody of 11/321, 624 is the same as that of the instant application, that is it is H460-22-1, he also states at paragraph 51, p. 24 that the “mouse monoclonal antibodies, H460-22-1..... were obtained following immunization of mice with cells from a patient's lung (1-1460-22-1)..... tumor biopsy”. Since this is not the method wherein the instantly claimed antibody was produced (with injection of both lung cancer tumor cells and a human lung large cell carcinoma cell line, see p. 43, lines 25-28 of 10/713,642) it cannot be determined if the antibodies are in fact the same. Even if it were to be found that the antibodies are indeed the same, the information presented in the 11/321, 624 application at paragraphs 51-55, Figure 14, and Figures 24-29 is not found persuasive, because there is no teaching that the antigen to which the antibody binds is differentially expressed in primary cancers compared to normal controls or that it is useful as an anticancer antibody.

For the reasons set forth previously in section 8 pages 4-12 of the Office Action of August 7, 2006 and above, Applicant's arguments have not been found persuasive and the rejection is maintained.

8. All other objections and rejections recited in Office Action of August 7, 2006 are withdrawn.

9. No claims allowed.

10. This action is a **final rejection** and is intended to close the prosecution of this application. Applicant's reply under 37 CFR 1.113 to this action is limited either to an appeal to

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the Board of Patent Appeals and Interferences or to an amendment complying with the requirements set forth below.

If applicant should desire to appeal any rejection made by the examiner, a Notice of Appeal must be filed within the period for reply identifying the rejected claim or claims appealed. The Notice of Appeal must be accompanied by the required appeal fee.

If applicant should desire to file an amendment, entry of a proposed amendment after final rejection cannot be made as a matter of right unless it merely cancels claims or complies with a formal requirement made earlier. Amendments touching the merits of the application which otherwise might not be proper may be admitted upon a showing a good and sufficient reasons why they are necessary and why they were not presented earlier.

A reply under 37 CFR 1.113 to a final rejection must include the appeal from, or cancellation of, each rejected claim. The filing of an amendment after final rejection, whether or not it is entered, does not stop the running of the statutory period for reply to the final rejection unless the examiner holds the claims to be in condition for allowance. Accordingly, if a Notice of Appeal has not been filed properly within the period for reply, or any extension of this period obtained under either 37.CFR 1.136(a) or (b), the application will become abandoned.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY

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ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Reddig whose telephone number is (571) 272-9031. The examiner can normally be reached on M-F 8:30 a.m.-5:00 p.m..

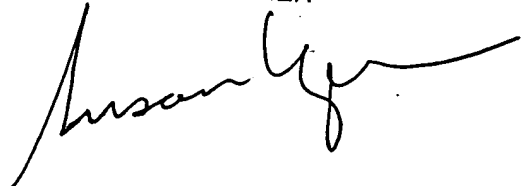
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on (571) 272-0890. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Peter J. Reddig, Ph.D.
Examiner
Art Unit 1642

PJR

SUSAN UNGAR, PH.D
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Susan Ungar', is written over the printed name and title of the Primary Examiner.